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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 966-0

December 13, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark Cohen, M.D.
Medical Director
Columbia Mammography Center
850 Columbia Rd.
Westlake, OH 44145

Facility I.D.#: 186130

Dear Dr. Cohen:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on September 28, 1999. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Your facility phantom quality control records were missing for five weeks for your facility mammography unit. Mammograms were performed on patients during these five weeks without the required weekly phantom film checks on the mammography units. **21 CFR 900.12(e)(2)**

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

The other item listed in your September 28, 1999 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violation noted in this letter;

- Each step your facility is taking to prevent the recurrence of similar violation;

- Sample records that demonstrate proper record keeping procedures related to quality control.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please note that this office received a letter, dated October 8, 1999 from you. Your letter adequately addressed the issues that are mentioned above. If you desire, you may respond with additional comment(s) to this Warning Letter. Otherwise, this office considers your October 8, 1999 as an answer to this Warning Letter.

If appropriate, please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Terri Eckert
Ohio Department of Health
Northeast District Office
Oliver R. Ocasek Government Office Building
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Charles W. Sedgwick
Acting District Director
Cincinnati District Office

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